COVID-19 Vaccine Information Sheet

Please read this information sheet carefully and ensure all your questions have been answered by a health care provider before receiving the vaccine.

What is COVID-19?

- COVID-19 is an infectious disease caused by a new coronavirus (SARS-CoV-2), recognized for the first time in December 2019 and declared a global pandemic in March 2020.
- The virus that causes COVID-19 is mainly passed from an infected person to others when the infected person coughs, sneezes, sings, talks or breathes.
- Infected people can spread the infection even if they **do not** have symptoms.
- Some people infected with the virus have no symptoms at all, while others have symptoms that range from mild to severe.
- Symptoms of COVID-19 can include cough, shortness of breath, fever, chills, tiredness, and loss of smell or taste.
- Individuals with mild symptoms may feel unwell for a long time after a COVID-19 infection.
- Unvaccinated people are at much higher risk of COVID-19 infection and serious illness, including hospitalization and death, compared to vaccinated people.

How does the COVID-19 vaccine protect against COVID-19 infection?

- The vaccine causes the body to produce **antibodies** to help prevent you from becoming sick if you are exposed to the COVID-19 virus.
- **Two** doses of the mRNA Pfizer-BioNTech Comirnaty COVID-19 vaccine can be 95% effective at protecting against symptomatic illness.
- **Two** doses of the mRNA Moderna Spikevax COVID-19 vaccine can be 86-94% effective at protecting against symptomatic illness.
- **Two** doses of the non-replicating viral vector vaccine AstraZeneca Vaxzevria and COVISHIELD) COVID-19 vaccine can be 62% effective at protecting against symptomatic illness.
- **Two** doses of the recombinant protein subunit vaccine Novavax Nuvaxoid COVID-19 vaccine can be 90% effective at protecting against symptomatic illness.
- **Two doses** of the plant based virus-like particle (VLP) vaccine Medicago Covifenz COVID-19 vaccine can be 71 % effective at preventing confirmed symptomatic COVID-19 disease.
- **One dose** of the non-replicating viral vaccine (Janssen) COVID-19 vaccine can be 67% effective at protecting against symptomatic illness.
- Some populations will require three doses of vaccine to complete a primary series and some populations may be eligible for a first or second booster dose. Please visit the Get the Shot page to review recommendations.
- It is important to note that the vaccine does not contain the virus so **you cannot get COVID-19 infection from the vaccine**.

Who can and cannot receive the COVID-19 vaccine?

- Public health officials will provide information on which individuals are able to receive the vaccine at this time.
- ***Table 1*** below has specific information regarding those who can and those who should not receive the COVID-19 vaccine.

Table 1: Summary Table of Those Who Can Receive the COVID-19 Vaccine, Those Who May Be Offered the COVID-19 Vaccine, and Those Who Should Not Receive the COVID-19 Vaccine

	INDIVIDUALS WHO **CAN RECEIVE** the COVID-19 Vaccine	INDIVIDUALS WHO **MAY BE OFFERED** the COVID-19 Vaccine Individuals in this category who are at high risk of exposure to COVID-19 infection should consult with their health care provider to discuss vaccination.	INDIVIDUALS WHO **SHOULD NOT RECEIVE** the COVID-19 Vaccine
Age	5 years of age and over **(Pfizer-BioNTech Comirnaty)** 6 years of age and over **(Moderna Spikevax)** 18 years of age and over **(AstraZeneca Vaxzevria, COVISHIELD, Janssen, Novavax Nuvaxovid*, Medicago Covifenz*)**	12 to 15 years of age **(Pfizer/BioNTech/Moderna)**	4 years of age and younger **(Pfizer-BioNTech Comirnaty)** 5 years of age and younger **(Moderna Spikevax)** 17 years of age and younger **(AstraZeneca Vaxzevria, COVISHIELD, Janssen, Novavax Nuvaxovid, Medicago Covifenz)** 65 years and older **(Medicago Covifenz)**
Currently experiencing symptoms that could be related to COVID-19			You should **not** be vaccinated if you have symptoms that could be due to COVID-19. If you are feeling unwell, complete the COVID-19 Self Assessment Tool or call 811 to arrange testing.
Current COVID-19 infection or past COVID-19 infection	You can be vaccinated if you are no longer infectious (10 days since first symptom or 10 days since positive test) and your symptoms have resolved.		You cannot be vaccinated while infectious (within 10 days of your first symptom or positive test). Attending a clinic while you are experiencing symptoms of COVID-19 may cause spread of infection to others.
Pregnancy	Currently pregnant or planning to become pregnant before receiving both doses of COVID-19 vaccine.		
Breastfeeding	Currently breastfeeding.		
Allergy to polyethylene glycol (Pfizer-BioNTech Comirnaty and Moderna Spikevax, Medicago Covifenz). Found in some cosmetics, skin care products, laxatives, cough syrups, bowel preparation products for colonoscopy, and some foods and drinks. **Allergy to polysorbate 80 (AstraZeneca Vaxzevria, COVISHIELD, Janssen and Novavax Nuvaxovid, Medicago Covifenz).** Found in medical preparations (e.g. vitamin oils, tablets, and anti-cancer agents), cosmetics. **Allergy to kanamycin and carbenicillin (Medicago Covifenz).** **Allergy to Tromethamine (Moderna Spikevax)** Found in some medications injected to do tests (contrast media) as well as other medications taken by mouth or injection, and some creams and lotions.			If you have been told you are allergic to polyethylene glycol (PEG)*, polysorbate 80, Tromethamine, or have had an allergic reaction from an unknown cause, you should not be vaccinated until it is determined to be safe by an allergist or other health care provider.
You had a severe reaction or allergic reaction to a previous dose of COVID-19 vaccine			If you had a serious or allergic reaction to your first dose of COVID-19 vaccine, you should not be vaccinated until it is determined to be safe by an allergist or other health care provider.

Have you had an allergic reaction to another vaccine (another type of COVID-19 vaccine or a non-COVID-19 vaccine) or other medication given by injection or intravenously in the past?			If "yes", you may receive a COVID-19 vaccine. You will be asked to wait in the clinic for 30 minutes after receiving the vaccine to make sure you are feeling well.
Do you have a history of blood clots with low platelets after a COVID-19 vaccine?			If you had blood clots with low platelet after a previous viral vector vaccine (AstraZeneca or Janssen), you should not receive the Janssen COVID-19 vaccine. Consult with your health care provider.
Do you have a history of blood clots?			Rarely blood clots have occurred after the Janssen vaccine. Discuss your risks with your health care provider.
Do you have a history of a problem with low platelets (a part of the blood that helps with clotting)?			Rarely low platelets can occur after the Janssen vaccine. If you already have a history of low platelets, you should consider receiving an mRNA vaccine. If you have a history of low platelets and choose to get the Janssen vaccine you should watch for easy bruising or excess bleeding that is unexplained. Your health care provider may monitor your blood platelet count after receiving the Janssen vaccine.
Have you previously experienced an episode of capillary leak syndrome (CLS)?			If "yes", you will be advised not to receive the **Janssen COVID-19 vaccine**. Consult with your health care provider.
Have you recently received monoclonal antibodies or convalescent plasma for treatment of COVID-19?			If "yes", you may be asked to delay receiving your COVID-19 vaccine.
Medical conditions Talk with your health care provider prior to vaccination if you are unsure about your medical conditions		Problems with your immune system, history of autoimmune conditions or currently taking medications/treatments.	

** The vaccine has not been studied well enough in the **"Generally Should Not Receive**" category. Therefore it is recommended to discuss with your primary health care provider if you are at high risk of exposure to COVID-19.*

** Polyethylene glycol (PEG) can rarely cause allergic reactions and is found in products such as medications, bowel preparation products for colonoscopy, laxatives, cough syrups, cosmetics, and skin creams, medical products used on the skin and during operations, toothpaste, contact lenses and contact lens solution. PEG also can be found in foods or drinks, but is not known to cause allergic reactions from foods or drinks.*

** **The safety and efficacy of Novavax Nuvaxovid and Medicago Covifenz have not been established in the following populations:***

- *Individuals previously infected with SARS-CoV-2;*
- *Individuals who are immunocompromised due to disease or treatment;*
- *Individuals who are pregnant or breastfeeding;*
- *Individuals who have an autoimmune condition.*

Informed consent should include discussion that there is currently limited evidence on the use of the Novavax Nuvaxovid and Medicago Covifenz vaccines in these populations

In addition to the information in *Table 1*, tell the health care provider if:

- **You have fainted or felt faint after receiving past vaccines or medical procedures.** Your health care provider may recommend that you receive the vaccine lying down to prevent fainting.
- **You have a bleeding disorder or are taking medication that could affect blood clotting.** This information will help the health care provider prevent bleeding or bruising from the needle.

How is the vaccine administered?

The vaccine is given as an injection into the muscle of the upper arm and will require two doses. It is important to receive both doses of the vaccine to ensure optimal protection from COVID-19 infection. The Janssen vaccine is a one-dose product however, NACI has recommended that a booster dose of an mRNA COVID-19 vaccine may be given to people who received the Janssen vaccine; the booster dose is given at least 6 months after the first dose.

What are the side effects of the vaccine?

Side effects are expected and can indicate the vaccine is working to protect you from COVID-19 infection. Side effects can develop in the days following the vaccination and can include one or more of the following:

- Pain, tenderness, and swelling where the needle was given
- Tiredness
- Headache
- Muscle pain
- Joint pain
- Nausea/vomiting/diarrhea
- Chills
- Fever
- Enlarged lymph nodes (swollen glands)
- Dizziness, decreased appetite, excessive sweating, itchy skin or rash

Myocarditis and Pericarditis

- There have been very rare reports of myocarditis and/or pericarditis following immunization with an mRNA COVID-19 vaccine product.
- Myocarditis is inflammation of the heart muscle and pericarditis is inflammation of the lining around the heart.
- Myocarditis and pericarditis has been reported more frequently in males, those under 30 years of age, and after a second dose.
- The majority of cases have been mild and individuals have recovered quickly.
- Seek immediate medical attention if you develop symptoms, which may include chest pain, shortness of breath, or the feeling of a fast, pounding or fluttering heartbeat.
- These symptoms typically occur within a week after the receipt of an mRNA vaccine dose.

Individuals with a history compatible with pericarditis who did not have any cardiac workup or had normal cardiac investigations can be revaccinated once:

- The individual is symptom-free and;
- At least 90 days has passed since vaccination

If another dose of COVID-19 vaccine is offered, the individual should receive the Pfizer-BioNTech 30mcg product due to the lower reported rate of myocarditis and/or pericarditis.

Informed consent should include discussion about the unknown risk of recurrence of myocarditis and/or pericarditis following receipt of additional doses of Pfizer-BioNTech COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine, as well as the need to seek immediate medical assessment and care should symptoms develop.

Some **rare reactions** that have been found to occur from taking a viral vector vaccine (AstraZeneca/COVISHIELD and Janssen) are:

Vaccine-induced immune thrombotic thrombocytopenia (VITT), also call thrombosis with thrombocytopenia syndrome (TTS)

- VITT is a serious condition involving thrombosis (blood clots) and thrombocytopenia (low platelets; platelets are a part of the blood used for clotting). VITT can cause blood clots to develop in the brain, abdomen, legs and other parts of the body. VITT symptoms can occur within 4 weeks, and sometimes up to 6 weeks, after vaccination.
- VITT has been reported to occur in about 1 in 300,000 people who receive a Janssen vaccine. VITT can result in death.
- Because of the risk of VITT, viral vector vaccines are not preferred.

Capillary leak syndrome (CLS)

- Capillary leak syndrome is serious and sometimes fatal condition that causes fluid to leak from small blood vessels causing rapid swelling of the arms and legs, sudden weight gain, and low blood pressures resulting in feeling faint.
- Those who have previously had capillary leak syndrome appear to be at increased risk following vaccination with a viral vector vaccine, such as Janssen.

Guillain-Barré syndrome (GBS)

- GBS is a potentially serious neurologic disorder that results in numbness and weakness in the arms, legs, face, chest or other muscles, causing paralysis in severe cases. It can occur within several weeks after vaccination with the Janssen vaccine.
- Most people fully recover from GBS but some have remaining symptoms and fatal cases can occur.

Seek medical care immediately if you develop these symptoms following immunization which could be associated with **vaccine-induced immune thrombosis with thrombocytopenia (VITT, TTS):**

- New severe headaches, worsening or persistent headaches; blurred vision, confusion or seizures
- Shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain
- Unusual skin bruising or pinpoint round spots under the skin beyond the site of vaccination

Seek medical care immediately if you develop these symptoms following immunization which could be associated with **capillary leak syndrome (CLS):**

- Rapid swelling of the arms and legs
- Sudden weight gain
- Feeling faint

Seek medical care immediately if you develop these symptoms after vaccination that could be associated with **Guillain-Barré Syndrome (GBS):**

- Numbness, weakness or inability to move the muscles in the arms, legs, face, chest or other muscles.

Allergic reactions are rare but can happen after receiving a vaccine. The immunization clinic staff are prepared to manage an allergic reaction should it occur. Symptoms of an allergic reaction include:

- Hives (bumps on the skin that are often very itchy)
- Swelling of your face, tongue or throat
- Difficulty breathing

What public health measures have been put in place to safely provide immunizations during COVID-19?
Health care providers are being very careful to prevent the spread of COVID-19 when offering immunizations. Examples of safety measures include the following:

- You will be asked about any COVID-19 symptoms when you arrive at the clinic. People with symptoms of COVID-19 should not attend the clinic.
- You will be asked to wear a mask while at the clinic and stay at least 6 feet away from others (except those in your household bubble).
- Staff will be wearing masks and cleaning their hands and work areas before and after each client.

What should you do before coming to the clinic?

- Wear a short-sleeve shirt or top with sleeves that are easy to roll up.
- To prevent feeling faint while being vaccinated, have something to eat before coming to the clinic.
- Bring your non-expired MCP card.
- Bring your immunization record with you and/or download the CANImmunize app to keep track of this and other vaccines.

What should you do after receiving the vaccine?

- **Wait for at least 15 minutes.**
- **Inform a health care provider** at the clinic if you feel unwell.
- **Call 9-1-1 right away if you develop any serious symptoms or symptoms of an allergic reaction.**
- **Continue to follow the recommendations of local public health officials** to prevent spread of COVID-19. Such as wearing a mask, staying at least 6 feet away from others and limiting social contacts.
- **Do not receive testing for tuberculosis (TB)** until at least 28 days after a COVID-19 vaccine (unless recommended by your health care provider).
- If possible, **wait at least two weeks after vaccination or completing your vaccination series before starting drugs that suppress your immune system** as recommended by your health care provider.
- **Keep your immunization record** with information about the COVID-19 vaccine in a safe place.

When should I return for my second dose?

- Two doses of COVID-19 vaccine will provide the best protection, if you are 30 years of age and older the **second dose should be booked at least 28 days and up to four months after the first dose**. If you are between the ages of 5 to 29 years, you should book your **second dose eight weeks after your first dose**.
- Emerging evidence suggests that a longer interval between the first and second dose of a primary series results in a stronger immune response and higher vaccine effectiveness and may also be associated with a lower risk of myocarditis and/or pericarditis in adolescents and young adults.

What vaccine will I receive for my second dose?

- An mRNA vaccine **is <u>preferred</u>** as the second dose for individuals who received a first dose of the AstraZeneca Vaxzevria/COVISHIELD vaccine, based on emerging evidence of better immune response from this mixed vaccine schedule and to mitigate the potential risk of VITT associated with viral vector vaccines.
- For those who received an mRNA COVID-19 vaccine (Pfizer-BioNTech Comirnaty or Moderna Spikevax), the same mRNA vaccine should be offered as the second dose if possible. If you present to a clinic that

does not have that vaccine available or you are unsure what vaccine you received as the first dose, either mRNA (Pfizer-BioNTech Comirnaty or Moderna Spikevax) vaccine can be offered.
- If you are between the ages of 12 and 29 years, the Pfizer-BioNTech Comirnaty vaccine is preferred.
- If you are 18 years of age or older and you are unable or unwilling to receive an mRNA vaccine, the Novavax Nuvaxovid vaccine may be offered as a second dose.

Am I eligible for a third dose of COVID-19 vaccine?

Some populations may require a third dose to complete a primary series. Please visit the Get the Shot page to review recommendations.

Am I eligible for booster doses of COVID-19 vaccine?

Certain individuals are eligible for first or second booster doses. To see if you are eligible for a booster dose, please visit the Get the Shot page to review recommendations.

If you decide to complete the series with AstraZeneca Vaxzevria/COVISHIELD vaccine, please consider the following information.

- **Effectiveness:** The same vaccine is generally used for all doses in a vaccine series because that is usually how the vaccine is studied by the vaccine companies. In clinical trials, the AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine prevented 60% to 80% of sickness from COVID-19 starting two weeks after the second dose. There was an even greater protection against hospitalization and death from COVID-19.

- **Side Effects:** Most reactions such as a headache and tiredness after getting AstraZeneca Vaxzevria/COVISHIELD vaccine are mild or moderate and short-lived. These side effects are rarer and even milder after the second dose of the vaccine.

- **Safety:** A very rare but serious condition of blood clots combined with low levels of blood platelets (Vaccine-Induced Immune Thrombotic Thrombocytopenia, or VITT) has been reported following immunization with AstraZeneca Vaxzevria/COVISHIELD or COVISHIELD vaccines in Europe, the United Kingdom, and Canada. These rare cases of VITT mostly happen between 4 and 28 days after the AstraZeneca Vaxzevria/COVISHIELD vaccine. People who get an AstraZeneca Vaxzevria/COVISHIELD vaccine should monitor for symptoms like severe and constant headache, belly pain, and difficulty breathing from 4 days to 42 days after the vaccine. In Canada, after the first dose, there has been one case of VITT reported for every 55,000 doses of vaccine given. The rate of VITT after a second dose is not clear yet, but after giving about 9 million second doses of AstraZeneca Vaxzevria/COVISHIELD vaccine, the United Kingdom has reported 15 VITT cases. This is 1 case per 600,000 doses, which is much rarer than after first doses, however it is possible this could change over time.

Completing the vaccine series with an mRNA or recombinant protein subunit (Novavax Nuvaxovid) vaccine:

- **Effectiveness:** Most studies looking at giving an mRNA vaccine after a first dose of AstraZeneca Vaxzevria/COVISHIELD are not finished yet, but one small study from Spain showed that immune response was greatly improved, compared with no second dose, when Pfizer vaccine was given 8 or more weeks after a dose of AstraZeneca Vaxzevria/COVISHIELD vaccine. It is possible that using different vaccines might stimulate the immune system in different ways and provide a stronger immune response, but we don't yet have studies that clearly prove this.

- **Side Effects:** A trial from the UK showed that people who got the Pfizer vaccine 4 weeks after a dose of AstraZeneca Vaxzevria/COVISHIELD vaccine had more general reactions like fever and aches than those

who received the same vaccine for their second dose. Most symptoms happened in the 2 days after immunization and went away on their own. In the study from Spain with AstraZeneca Vaxzevria/COVISHIELD and then Pfizer after 8 weeks, side effects were mild and went away on their own.

- **Safety:** There have been no cases of VITT reported in NL after receiving an mRNA vaccine. There are no safety signals from either the UK trial or the one in Spain that gave people an mRNA vaccine after an AstraZeneca Vaxzevria/COVISHIELD vaccine, however these trials were very small and there is less data on mixed vaccine series than on vaccine series with the same vaccine.

Currently, mRNA, AstraZeneca Vaxzevria/COVISHIELD, and Novavax Nuvaxovid vaccines are available in Newfoundland and Labrador. Therefore, those who wish to have a second dose with a mRNA or Novavax Nuvaxovid vaccine will not be delayed in receiving that vaccine. If a person chooses an mRNA or the Novavax Nuvaxovid vaccine for their second dose, they do not need to restart a series. If a person needs help with understanding the information above, they may contact a healthcare professional.